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10/677,420

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EXAMINER

SEVILLA, CHRISTIAN ANTHONY

ART UNIT

PAPER NUMBER

3775

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/677,420	Applicant(s) KIENZLE ET AL.	
	Examiner CHRISTIAN SEVILLA	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/5/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants argue burden has not been established regarding the restriction to one of claims 1-23 (Group I) drawn to a system for tracking the position of an instrument relative to an area of interest and claim 24 (Group II) drawn to a method for using an electromagnetic localizing system. In response, burden exists because Group I and Group II have a separate status in the art when the inventions are classifiable together (See MPEP § 802.02, item B). For instance, claim 1 is directed a stereotactic device whereas claim 24 is directed to a method of using a stereotactic device. US 5891158 is evidence of separate inventive effort in methods of using a stereotactic device. US 6887247 is evidence of separate inventive effort in stereotactic devices.

Applicants argue burden has not been established regarding the restriction to one of claims 1-12 (Group I-A) drawn to a system for tracking the position of an instrument relative to an area of interest and claims 13-23 (Group II-A) drawn to a tracking system. In the instant case, burden exists because Group I-A and Group II-B have a separate status in the art when the inventions are classifiable together (See MPEP § 802.02, item B). For instance, claim 1 does not require a computer system whereas claim 13 requires a computer system. US 3053256 is evidence of separate inventive effort in stereotactic systems that do not utilize computer systems. US 5891034 is evidence of separate inventive effort in stereotactic systems that utilize computer systems.

The requirement is still deemed proper and is therefore made FINAL.

Response to Arguments

Applicants argue the Williams reference fails to anticipate each and every element of claim 1 because "nowhere in Williams is there any teaching that Williams' reference arc tracking means 18/20 is movable relative to the area of interest" (pp. 10-11). The Examiner respectfully disagrees. The reference arc tracking means 18/20 is movable relative to an area of interest because Mayfield clamp 16, which supports reference art tracking means 18/20, can be moved relative to bone.

Applicants argue the Williams reference fails to anticipate each and every element of claim 1 because "Williams fails to teach that its tracking head 34 communicates with its reference arc tracking means 18/20" (pp. 10-11). The Examiner respectfully disagrees. First, claim 1 does not require that the first localizer and the second localizer are in communication with each other (claim 1, line 10; claim 8). Second, the first localizer (34) and the second localizer (20) can be considered to be "in communication" because the relative positions of the first localizer (34) and second localizer (20) are known (col. 3, lines 28-34; col. 4, lines 28-41; col. 7, lines 48-53).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 8, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams (US 6190395).

Regarding claim 1, Williams discloses an instrument (32); an instrument guide (44) mounted to the instrument, the instrument guide carrying a first localizer (34) proximate the instrument, the first localizer being movable relative to the instrument; and a fixator (16), the fixator configured to be attached to an area of interest, the fixator carrying a second localizer (20) proximate the area of interest, the first and second localizers being movable in order that the first and second localizers are in communication such that the position of one of the localizers is known relative to the position of the other of the first and second localizers.

Regarding claim 3, Williams discloses an imaging device (24) that takes images of the area of interest, the images being stored on a computer system (28) capable of calculating the position of the second localizer on the images and calculates the position of the first localizer relative to the images {col. 4, lines 28-37}.

Regarding claim 7, Williams discloses the instrument is a surgical drill guide and the area of interest is an area of a patient's body, the first and second localizers being connected to a computer (28) carrying images of the area of interest, the computer analyzing the communication between the first and second localizers to calculate the position of the instrument relative to said images.

Regarding claim 8, Williams discloses the first and second localizers are light emitting diodes {col. 5, lines 3; col. 4, line 19}.

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Regarding claim 11, Williams discloses the position of the first localizer relative to the instrument and the position of the second localizer relative to the fixator may be adjusted {e.g., via clamping band 26 or Mayfield clamp 16} such that the positions of the first and second localizers relative to each other may be adjusted to optimize communication therebetween.

Regarding claim 12, Williams discloses the position of the first localizer relative to the instrument and the position of the second localizer relative to the fixator may be adjusted {e.g., via clamping band 26 or Mayfield clamp 16} such that the positions of the first and second localizers relative to a third localizer (24) may be being adjusted to optimize communication between the three localizers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Sati, *et al.* (US 2002/0055679; "Sati" herein).

Williams discloses the second localizer (20) is an electromagnetic transmitter (e.g., LED emitters; col. 4, line 19).

Williams fails to disclose the first localizer (34) is an electromagnetic receiver; and the transmitter and receiver being connected to a computer that analyzes the communications therebetween to calculate the position of the receiver relative to the transmitter.

Sati discloses a medical device in which objects to be tracked include markers which can be configured to emit, receive, or reflect energy {para. [0010], lines 6-8}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Sati to include the first localizer (34) is an electromagnetic receiver; and the transmitter and receiver being connected to a computer that analyzes the communications therebetween to calculate the position of the receiver relative to the transmitter. Doing so would have permitted taking additional measurements related to object position, thereby permitting more precise determination of position.

Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Schenk, *et al.* (US 5895389; "Schenk" herein).

Regarding claim 4, Williams discloses the instrument guide include a localizer assembly (34, 50). The localizer assembly carries the first localizer (34).

Williams fails to disclose the instrument guide includes a handle assembly connected to the localizer assembly at concentric collars, the collars receiving the instrument along a longitudinal axis, the collars being rotatable relative to each other

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such that the first localizer is rotatable about the longitudinal axis relative to the instrument and handle assembly.

Schenk discloses a collapsible drilling guide wherein a plunger (30) telescopically slides in a sleeve (10) {col. 4, lines 41-44}; a handle (24) secured to the sleeve by two pins (26) {col. 4, lines 32-34}; and scale (44) graduates the outside of the plunger (30) to indicate the amount by which the guide has been collapsed {col. 5, lines 16-17}.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Schenk to construct the instrument guide includes a handle assembly connected to the localizer assembly at concentric collars, the collars receiving the instrument along a longitudinal axis, the collars being rotatable relative to each other such that the first localizer is rotatable about the longitudinal axis relative to the instrument and handle assembly. Doing so would have enabled a surgeon to more precisely determine drilling depth, thereby preventing the drill from extending too deeply into bone.

Regarding claim 10, Williams discloses the instrument guide include a localizer assembly (34, 50). The localizer assembly carries the first localizer (34).

Williams fails to disclose the instrument guide includes a handle assembly connected to a first collar and the localizer assembly carrying the first localizer and being connected to a second collar, the first and second collars being connected and concentrically aligned and receiving the instrument, the first and second collars being configured to move relative to each other about the instrument.

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Schenk discloses a collapsible drilling guide wherein a plunger (30) telescopically slides in a sleeve (10) {col. 4, lines 41-44}; a handle (24) secured to the sleeve by two pins (26) {col. 4, lines 32-34}; and scale (44) graduates the outside of the plunger (30) to indicate the amount by which the guide has been collapsed {col. 5, lines 16-17}.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Schenk to construct the instrument guide so that it includes a handle assembly connected to a first collar and a localizer assembly carrying the first localizer and being connected to a second collar, the first and second collars being connected and concentrically aligned and receiving the instrument, the first and second collars being configured to move relative to each other about the instrument. Doing so would have enabled a surgeon to more precisely determine drilling depth, thereby preventing the drill from extending too deeply into bone.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Haynes (US 2238870).

Regarding claim 5, Williams fails to disclose the fixator includes a block receiving screws in channels therein, the second localizer being connected to the block and the screws being inserted into the area of interest, the block being adjustable along the screws in order to adjust the position of the second localizer relative to the area of interest.

Haynes discloses a base member (3) with screws (4) that pass through spaced openings (5) in the base member {Fig. 2}.

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It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Haynes in order that the fixator includes a block receiving screws in channels therein, the second localizer being connected to the block and the screws being inserted into the area of interest, the block being adjustable along the screws in order to adjust the position of the second localizer relative to the area of interest. Doing so would have permitted affixation of the fixator and, thus, the localizer, to bone in a more secure manner, thereby further preventing unwanted shifting of the second localizer.

Regarding claim 6, Williams fails to disclose the fixator includes a block connected to the area of interest, the fixator further including first and second clamps and a post, the first and second clamps being adjustably connected to the block and the post being adjustably connected to the first and second clamps, the post receiving the second localizer such that the second localizer is adjustable relative to the block along the first and second clamps and the post.

Haynes discloses a base member (3) with screws (4) that pass through spaced openings (5) in the base member {Fig. 2}; a post (9); first and second clamps (18, 19); the first and second clamps being adjustably connected to the block {member 8 forms part of a ball and socket connection; p. 1, right col., lines 18-20; Fig. 3}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Haynes in order that the fixator includes a block connected to the area of interest, the fixator further including first and second clamps and a post, the first and second clamps being adjustably connected to

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the block and the post being adjustably connected to the first and second clamps, the post receiving the second localizer such that the second localizer is adjustable relative to the block along the first and second clamps and the post. Doing so would have permitted immobilizing the ends of bone fragments for the purpose of reducing a bone fracture, thus adapting the device for use in a wider range of surgical applications.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Davison (US 4710075).

Williams fails to disclose fixator includes a post, the post having a shaft with a spring and dowel mechanism thereon, the second localizer receiving the shaft such that the dowel engages the second localizer and the spring is loaded between the second localizer and the post to secure the second localizer to the post.

Davison discloses a medical device in which a first member (26) is slidably disposed over a second member (16) {Figs. 1 & 4; col. 4, lines 31-36}. A coil spring (60) is disposed in a cavity (40) such that the spring biases a plunger (44). Ridges (48) on the plunger are selectively received into grooves (20) in the second member.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Davison in order that the fixator includes a post, the post having a shaft with a spring and dowel mechanism thereon, the second localizer receiving the shaft such that the dowel engages the second localizer and the spring is loaded between the second localizer and the post to secure the second localizer to the post. Doing so would have increased the level of separability between the fixator and

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the second localizer, thereby facilitating quicker replacement of the second localizer for the purpose of repair or improvement.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775